Patenting Indian medicinal plants and products

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Abstract

India possess rich heritage of valuable Fauna and hence has been considered as a 'treasure house' of valuable medicinal and aromatic plant species. The Ministry of Environment and Forests, Government of India have identified and documented over 9,500 plant species considering their importance in the pharmaceutical industry. Out of these, about 65 plants have large and consistent demand in world trade. Use of plants as a source of medicine has been inherited and is an important component of the health care system in India. India has 16 Agro climatic zones, 45,000 diverse plant species out of which 15,000 are medicinal plants. The Indian Systems of Medicine have identified 1500 medicinal plants, of which 500 species are mostly used in the preparation of drugs. The Indian Systems of Medicine, particularly Ayurveda, Siddha, Unani, & Homoeopathy medicine largely use plant base materials, minerals, metals, marine and products of animal origin. Our ancient texts had documented medicinal uses of a large number of plants. These plants are being used for preparation of medicines for centuries. A new trend has, however, been noticed that foreign countries have exposed interest in medicinal plants accessible in India and well documented in our books signifying the formulation in which they are used. A number of medicinal plants and their uses have been patented by foreign countries. There has been condemnation by the people on this mounting trend of patenting of our medicinal plants and their uses. Some of the well-known plants Kala Zeera, Amaltas, Indian Mustared, Karela, Brinjal, Neem, Gudmar etc. have patents. A number of of the patents have been effectively contested by India. India is behind the rest of the world in patents both quantitatively and qualitatively, even when comparison is made with our neighbour China. The persistent illiteracy and confusion about patents is a serious matter. Our pool of knowledge that is protected by patents, even in areas where we have a competitive advantage is rather poor. Take the area of herbal products, where so much emotion has been raised. The number of herbal patents (1995-1998) was 1889, out of which China had a share of 889, and the Indian share was next to nothing. This paper explores the need to document the indigenous knowledge related to Indian herbs and plants and their medicinal and other uses and convert it into easily navigable computerize data base for easy access and to secure patenting rights; to discourage other countries for patenting Indian heritage.

Keywords: Fauna, Ayurveda, Siddha, Unani, Homoeopathy medicine, patenting rights.

Introduction

India is one among the twelve mega diversity countries, commanding 7% of the world's biodiversity and supporting 16% of the major forest types, varying from alpine pastures in the Himalayas to temperate, sub-tropical, tropical forests, and mangroves in the coastal areas. Two of the world's 18 hotspots of bio-diversity are found in India and thus have supremacy over 89,451 animal species accounting for 7.31% of the faunal species in the world and the flora accounts for 10.78% of the global total. The endemism (*Endemism – Nativeness by virtue of originating or occurring naturally (as in a particular place) -the quality of belonging to or being connected with a certain place or region by virtue of birth or origin)* of Indian biodiversity is high - about 33% of the country's recorded flora are endemic to the country and are concentrated mainly in the Northeast, Western Ghats, North-West Himalayas and the Andaman and Nicobar islands. The country possess16 Agro climatic zones, 45,000 diverse plant species out of which 15,000 are medicinal plants of which 500 species are mostly used in the preparation of drugs (Table 1). The World Health Organization (WHO) estimates that 80 percent of the world population presently uses herbal medicine for some aspect of primary health care. Herbal medicine is a major component in all indigenous peoples' traditional medicine and a common element in Ayurvedic, homeopathic, naturopathic and traditional oriental. Major pharmaceutical companies are currently conducting extensive research on plant materials gathered from the rain forests and other places for their potential medicinal value. Substances derived from the plants remain the basis for a large proportion of the commercial medications used today for the treatment of heart disease, high blood pressure, pain, asthma, and other problems (Table 2).

Medicinal plants are the local inheritance with global importance:

The Indian Systems of Medicine, particularly Ayurveda, Siddha, Unani, & Homoeopathy medicine largely use plant base materials, minerals, metals, marine and products of animal origin. Our ancient texts had documented medicinal uses of a large number of plants. These plants are being used for preparation of medicines for centuries. The traditional Medicinal plants have successfully set an example of natural resource use in curing many complex diseases for more than 3,000 years. The plants used for various therapies are readily available, are easy to transport, and have a relatively long shelf life. The most important advantage of herbal medicine is the minimal side effects, and relatively low

Table 1. Distribution of medicinal plants.

Country or region	Total number of native species in flora	No of medicinal plant species reported	% of medicinal plants
World	297000	52885	10
India	17000	7500	44
Himalayas	8000	1748	22

cost compared to the synthetic medicines. The success of medicinal plants sector mainly depends on the awareness and interest of the farmers as well as its other stakeholders, supportive government protection policies, availability of assured markets, profitable price levels, and suitable agro-techniques. The World Health Organization (WHO) has estimated the present demand for medicinal plants is approximately US $14 billion per year. The demand for medicinal plant-based raw materials is growing at the rate of 15 to 25% annually, and according to an estimate of WHO, the demand for medicinal plants is likely to increase more than US $5 trillion in 2050. In India, the medicinal plant-related trade is estimated to be approximately US $1 billion per year. According to an estimate, the quantity of export of Ayurvedic products produced in India has tripled between last two financial years (2001-2002 and 2002-2003 (Table 3).

Bio-piracy: Bane for developing countries:

The earlier secluded green forests have currently become component of a vibrant, profit-seeking economy and challenging pluralistic political principles worldwide. Medicinal plants signify not only a valuable part of India's biodiversity but also a foundation of immense conventional knowledge. Knowledge-rich companies and researchers from the industrial world have been attracted to the wealth of the poorer countries have in their biodiversity and the traditional knowledge systems. Some argue that the access to such biodiversity and community knowledge by the industrially developed nations is essential for the larger welfare of mankind as this advances knowledge and leads to innovative products which contribute to the well being of global consumers. The point is that this access to the resources of the poor does not benefit in any way, while their natural resources and intellectual property continues to be appropriated and monopolized. The patenting (*A patent may be granted for a new, useful, and non-obvious invention, and gives the patent holder a right to prevent others from practicing the invention without a license from the inventor for a certain period of time (typically 20 years from the filing date of a patent application)* of indigenous knowledge by foreign corporations is a cultural threat to countries like India as well as economic loss. Developing countries increasingly

Table 2. Botanical name of the medicinal plant/product/ common name.

		Medicinal use
Abromaaugulata Lam.	Devil's cotton (Sivapputtutti.)	Uterine tonic regulates menstrualflow; urinary trouble, bronchitis, broncho-pneumonia, carbuncles and poisonous boils; *Leaf:* used in diabetes, rheumatic pain and sinusitis.
Acoruscolamus Linn	The sweet flag. (Vasamboo)	Laxative, diuretic, carminative; improves voice and appetite; good for oral diseases, abdominal pain, epilepsy, bronchitis, hysteria, loss of memory, rat bite and worms in ear.
Aeglemarmelos Corr	Wood apple, Bael tree.(Vilvam)	Destroys phlegm and a *good* remedy in fevers associated with catarrhal symptoms, also good for dropsy, bleeding piles, dysentery, diarrhoea, bowel complaints and is a good laxative.
Balanitesaegyptica (L.)	Desert date, Soapberrytree, Thorn tree.(Nanjunda)	Bark, Leaf, Fruit and Seed: as anthelmintic and purgative; Fruit: in boils, leucoderma and other skin diseases; Fruit-pulp: in whooping cough.
Butea monosperma	Flame of the forest, Parrot tree. (Samithu, Palasam)	Gum: in diarrhoea; Bark: as haemostatic, in wounds, Flower: in eye complaints; antifertility.
Catharanthus roseus (L.)	Madagascar periwinkle, Old maid, Red Periwinkle (Sudukadu Mallikai;	Root-paste: in septic wounds Leaf-juice: in blood dysentery Root: in cancerous wounds
Embelia ribes Burm	Embelia, Embelia fruit(Vayuvilanga)	Stomach pain and increases exothermic metabolism; useful in skin diseases including leprosy.
Ficus racemosa L	Cluster fig, Country fig, Gular fig.(Atti, Aththi)	Useful in antifertility, pimples and wounds;
Gymnema sylvestre	Vine, Periploca of the woods (Sakkaraikkolli, Shirukurinja)	Useful in amennorrhoea, asthma, bronchitis, cardiopathy,conjunctivitis,constipation,cough,dyspepsia,haemorroids,hepatosplenomegaly,inflammations, intermittant fever, jaundice and leucoderma
Vetiveria zizanioides	Cuscusn root(vetiver)	amenorrhea, antifertility,
Terminalia chebula, Terminalia reticulata	Indian Gall Nut (Kadukka)	Remunerative, tonic, astringent, laxative, nervine, expectorant, anthelmintic, alterative

Source: Somasundaram.S, Ethno botany, 2004.

face biopiracy *(Biopiracy' describes a process in which living resources or traditional knowledge and practices are patented, thus applying intellectual property restrictions to their use)* as a significant issue that immediately needs to be addressed. Since many of these countries are shelters of biodiversity and rely economically on their ability to export indigenous products and processes, they see the rising importance of protecting their traditional knowledge from unjustifiable foreign patenting.

Table 3. Export of medicinal produts (USD million).

Year	Medicinal plants	Ayurvedic products
1999-2000	79.65	33.51
2000-2001	112.46	48.57
2001-2002	133.38	50.45
2002-2003	124.85	154.11

Source: National medicinal plants board, government of India

The World Trade Organization (WTO) is encouraging developing countries to expand their legal protection of intellectual property rights in order to be on a similar "playing field" with the developed countries. Hence India, as a biodiversity hotspot, is taking a leading role it committing to the protection of its knowledge base. The tribulations experienced in case of patents on the turmeric, neem, basmati etc also highlight the problem of bio-piracy- and demand for patenting of indigenous bio-diversity- related knowledge. Further, a new trend is that foreign countries have exposed interest in medicinal plants accessible in India and well documented in our books signifying the formulation in which they are used. A number of medicinal plants and their uses have been patented by foreign countries.

Medicinal plants are a significant target of patent claims since they have become of immense significance to the international drug and cosmetic industries. This is due to the increasing occurrence of allergic reaction in the west to chemical drugs, and the complications arising from side effects after prolonged drug use in chronic illnesses. The global drug industry, spurred by the accomplishment of plant based cancer cures like Vinblastine, Vincristine and now Taxol, has intensified its search of the plant world for potential drugs. Because of this international awareness, illegal prospecting for medicinal plants has been carried out in developing countries on a large and unsustainable scale. But, India is behind the rest of the world in patents both quantitatively and qualitatively, even when comparison is made with our neighbor China. The persistent illiteracy and confusion about patents is a serious matter. Our pool of knowledge that is protected by patents, even in areas where we have a competitive advantage is rather poor. Take the area of herbal products, where so much emotion has been raised. The number of herbal patents (1995-1998) was 1889, out of which China had a share of 889, and the Indian share was next to nothing. Different ways and systems for awarding patents on the medicinal plants in India, United States, Europe, Canada and other countries have widened the confusion. In many countries, the plants and inventions directed to the plants and the plant products (i.e., seeds, flowers, gums, and resins) are not eligible for filing a patent. In United States, however, any living organism derived by human invention, such as by breeding or by laboratory-based manipulation, can be filed for awarding patent. The Indian Protection of Plant Varieties and Farmers Rights Act of 2001 recognize the contribution of farmers who actively participate in the breeding programs. Furthermore, this act contains provisions for benefit sharing whereby local communities are acknowledged as a contributor of plants. Now that a reasonable level of consciousness has been generated concerning the sort of IPR regime that the GATT/ TRIPs have heaped upon developing countries. It necessitates defining our positions on all our biological resources like microorganisms and medicinal plants which along with seeds will be in the forefront of IPR claims. Unfortunately, there is a wide gap between developed and developing nations such as India on patenting the products. For example, out of the 3,125,603 patents filed in 91 countries, only 301,177 or 9.6% are registered in developing countries while the rest is in industrialized countries. Of these, only 0.2% of the total and 2.3% of those registered in developing countries belong to residents. In addition, 97.7% of the total patents filed thus far are in the name of non-residents, who apply solely to control export markets in developing countries.

Developing nations and many scientists who want to exploit medicinal plants demand more specific rules about

Table 4. Major institutions involved in funding projects to the medicinal plants research in India.

Institutions	Funding for major areas in medicinal plants research
National medicinal plants board, NMPB	Survey, documentation, cultivation, marketing, conservation
Department of science & technology, DST	Taxonomy, ecology, pathology, survey, propagation, documentation, cultivation, conservation
Council for scientific & industrial research, CSIR	Ecology, taxonomy, biochemistry, survey, documentation, cultivation, genetics, agro-technology, conservation
Indian council of medical research, ICMR	Breeding, value addition
All India council for technical education, AICTE	Management technology
Department of biotechnology, DBT	Agro-technology, molecular biology, biochemistry, rural bio-technology
Defense research & development organization, DRDO	Agro-technology, survey, documentation, conservation
Indian council of agricultural research, ICAR	Breeding, pathology, molecular biology
Ministry of environment & forest, MoEF	Survey, documentation, conservation, management, ecological impact assessment, cultivation
National bank for agriculture and rural development, NABARD	Cultivation, marketing
University grant commission, UGC	Ecology, biochemistry, survey, documentation
Herbal research and development institute, HRDI	Survey, documentation, nursery development
G.B. Pant institute of himalayan environment & development, GBPIHED	Survey, documentation, cultivation, conservation

Source: Journal of Ethno biology and Ethno medicine 2006.

the recording of nationality of samples and sharing of their benefits between the nations of origin, the inventor, and the commercial sponsors. Some developed nations are not inclined to accept such provisions. These conflicts have frustrated many scientists who believe that natural products remain the most promising source for new drugs. Besides government agencies, there are numbers of stakeholders ranging from herb gatherers, local middlemen, urban traders, wholesalers, manufacturers, exporters and herbal healers in the medicinal plants trade sector. The marketing system in medicinal plants sector is largely unregulated and inequitable. The medicinal plant collectors are generally the marginal farmers and laborers. They get cash income to meet their basic requirements for food, health and children education by selling medicinal plants. They are often unaware about the real market prices of many medicinal plant species. Generally, in medicinal plants sector, there is a top down approach and even the many stakeholders at the bottom are not aware of the rising demand of their product and the availability of its market. For example, in some villages of Chamoli district of Uttaranchal, the farmers had cultivated Kut (Saussurea costus) and Dolu (Rheum emodi) but they were unable to sell them due to lack of knowledge on the marketing system. Conversely, many medicinal plant species are traded through illegal channels.

The other constraints in the medicinal plants sector are:

1) slow rate of production of many medicinal plants, 2) long gestation period, 3) shortage of suitable cultivation technology, 4) production of small quantity, 5) unscientific harvesting, 6) paucity of research on the high yielding varieties, 7) inefficient processing techniques, 8) fluctuation in demand and supply, 9) poor quality control procedures, 10) scarcity of good manufacturers, (11) poor marketing infrastructure, and 12) poor coordination among different stakeholders,13)the medicinal plant sector is largely less documented and inadequately regulated

Avenues in support of medicinal plants sector:

A high diversity of medicinal plants would be helpful for further scientific research on exploring their medical efficacy, value addition, and use in curing various old and new diseases. India has already established a reputation as a low-cost manufacturer of high quality generic drugs in the global market. This fact can be used as an important tool for the marketing of herbal products produced in India.

Existing policies: In the National Five Year Plans of India, the medicinal plants sector has been identified as an integral part of the Indian System of Medicine and Homeopathy In 1983, the National Health Policy recognized that the large stock of health manpower in Ayurveda, Siddha, Unani, Homeopathy and Naturopathy had not been adequately utilized; therefore, steps need to be taken to move towards a meaningful integration of the indigenous and modern systems of medicine. The Planning Commission and the National Medicinal Plants Board (NMPB) of the Government of India have prepared a policy document on the promotional and commercial aspects of the medicinal plants. The various policies at national and state level and their subsequent implementation will provide an opportunity in the advancement of medicinal plants sector.

Institutional support: In India, many government and non-government organizations have had the focused attention on improving the medicinal plants sector. The successful establishments of medicinal plants sector may help in raising rural employment, boost commerce around the world, and contribute to the health of millions.

Traditional Knowledge Digital Bank (TKDL): The government of India has set up a Traditional Knowledge & Digital Library (TKDL), namely, an electronic database of traditional knowledge in the field of medicinal plants. Such a database would enable the Patent Officers all over the world to search and examine any prevalent use/prior art, and thereby prevent incorrect grant of patent based on knowledge in public domain, including knowledge associated with medicinal plants. The issue had also been taken up at the international level in the Inter Government Committee of the World Intellectual Property Organization to ensure that TKDL is prescribed as a non-patent literature and minimum PCT documentation to ensure that patent examiners are duty bound to search the said database for any prior art.

Proposal for conservation of conventional Knowledge: India ought to set into action the drafting of suitable legislations to guarantee that the laws we devise permit us to keep hold of power over our biological resources and be acquainted with the privileges of local and indigenous communities as owners of these bio-resources. In countries like Australia and the Philippines, strong national laws have been passed for the protection of local genetic resources. These laws establish the ownership of communities over the biological resources of their region and recognize their right to share in the profits of products derived from indigenous knowledge.

There is a need to document the indigenous knowledge related to Indian herbs and plants and their medicinal and other uses and convert it into easily navigable computerize data base for easy access and to secure patenting rights; to discourage other countries for patenting Indian heritage. Along with the documentation of the bioresources, we must document the local/ community knowledge that exists about the various uses of these resources. This documentation which should be compiled as a National Bio-resource Register will provide several functions. The first is that of a data bank for people seeking access to information. This access should be made available for a fee accompanied by the conditions governing the use of this information.

Conclusion

It is high time that India drafts legislations that will ensure protection for its medicinal plants and lays down policy guidelines for the commercial use and exploitation of this resource. These policy guidelines will have to be such that the commercial use of this bio-resource is both sustainable and equitable. The latter means recognizing the contribution and therefore the rights of indigenous communities. It is expected that India should aim to build a golden triangle between traditional medicine, modern medicine, and modern science which will be a boon for developing the traditional herbal medicine and the medicinal plants sector.